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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/011,855	12/04/2001	Russell Baumann	034827-0702	5245

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EXAMINER

LI, BAO Q

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 05/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/011,855	Applicant(s) BAUMANN ET AL.	
	Examiner Bao Qun Li	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 February 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 8-22 is/are pending in the application.
- 4a) Of the above claim(s) 14-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 8-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 14-22 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1 and 8-22 are pending.

Response to Amendment

This is a response to the amendment, paper No. 11, filed 02/11/04. Claims 1 and 9-13 have been amended. Claims 2-7 have been canceled. New claims 14-22 have been added. Claims 1 and 8-22 are pending before the examiner. Claims 1 and 8-13 are considered before the examiner.

Please note any ground of rejection(s) that has not been repeated is removed. Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Election/Restrictions

1. Newly submitted claims 14-22 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the method differs from the elected method is that they use different sequence probe and different procedure for detecting the HCV amplicon.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 18-22 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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2. Claims 1, 8 and 11-13 are still rejected under 35 U.S.C. 103(a) as being unpatentable over Kleiber et al. (J of Molecular. Diagnosis, 2000, Vol. 2, No. 3, pp. 158-166), Kawai et al. (Journal of Medical Virology 1999, Vol.58, pp. 121-126), Resnick et al. (US Patent No. 5,527,566A), Michinori et al. (JP 103899-A/1), Scherer G. (Nucleic Acids Res. 1978, Vol. 5, pp. 3141-3156) and Lee et al. (US Patent NO. 6,316,610B2) on the same ground as stated in the previous Office Action.

3. Applicants traverse the rejection and assert that a prima facie case of obviousness has not been established because none of the above cited references, taken singly or in combination, teach or suggest all of the recited limitations of the present claimed invention.

4. Applicants' argument has been respectfully considered; however, it is not found persuasive because the claimed invention is drawn to a method of detecting hepatitis C virus (HCV) in a biological sample by using PCR plus a fluorescent labeled probe for detecting the final amplified PCR product. The assay employs 5'-3' nuclease to cleave the double fluorescent dyes labeled probe during the PCR/hybridization assay. This assay is well described in the art by Kleiber et al. While claimed invention uses different HCV probe, primer and fluorescent dye, these limitation is fully disclosed by other in the field. For example, Resnick et al. teach a pair of primers for detecting the presence of HCV RNA by PCR, which are 100% identical to the SEQ ID NO: 1 and 2. Michinori et al. disclose a probe of SEQ ID NO: 1 comprising the nucleic acid sequence that is 100% identity to the claimed probe of SEQ ID NO 3. The said probe is also used for detection of HCV RNA suitable for a fluorescence dye labeling (see line7 of page 6, Office apologized for citing and giving the wrong page of the reference).

5. Because the entire sequence of HCV is disclosed in the cited references prior to the current Application was filed, it would be obvious for a person with ordinary skill in the art to be motivated to generate many oligonucleotide probes according to the disclosure of Resnick et al and Michinori et al. which includes the selection of a primer consisting of SEQ ID NO: 1 and 2 and probe of SEQ ID NO: 3. Since it is well know for any ordinary skill artisan that any probe selected from a known sequence is able to hybridize with its complementary sequence. In the instant case, as Applicants do not provide a special reason why SEQ ID Nos 1, 2 and 3 are selected over other probes that can be selected according to the known sequence of HCV in the art, the claimed invention as a whole is prima facie obvious absent unexpected results

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Conclusion

Claims 1, 8 and 11-13 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 571-272-0904. The examiner can normally be reached on 7:00 to 4:00.

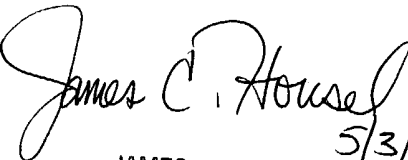
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Bao Qun Li

Art Unit 1648

April 29, 2009


JAMES HOUSEL
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600
5/3/04